

REMARKS

Claims 1 - 42 and 47 - 60 have been withdrawn from consideration. Claims 43 - 46 remain pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 43, 44 and 46 stand rejected under 35 U.S.C. § 103 as obvious over Fig. 9 of Desai (U.S. Patent No. 5,857,464) in view of Leidich (U.S. Patent No. 584,091). The Examiner stated, in support of the rejection, that Figure 9 of Desai discloses all limitations of claims 43, 44, and 46 except for the element of a generally hemispherical portion, but that Leidich discloses such an element.

Claim 43 recites a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen."

As an initial matter, Applicants submit that the Leidich Patent is *non-analogous* to Applicants' invention, and as such, cannot be relied on to reject claims 43 - 46 under 35

U.S.C. § 103(a). The Examiner is directed to a two-step test for determining whether a prior reference is non-analogous and thus not relevant in determining obviousness. The first step is to determine whether the reference is "within the field of inventor's endeavor". In re Deminski, 230 U.S.P.Q. 313 (Fed.Cir. 1986). If it is not, then a determination must be made as to whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved". Id., Strateflex, Inc. v. Aeroquip Corp., 713 F.2d 1530 (Fed. Cir. 1985); also see In re Oetiker, 977 F.2d 1443, 1447 (Fed.Cir. 1992). If this answer is also "no", the reference is deemed non-analogous; therefore it cannot be used for determining obviousness. As indicated above, Applicants respectfully submit that the Leidich Patent constitutes non-analogous art, and thus should not be used as a reference for a Section 103 rejection.

Analyzing the first step of the non-analogous art test, Applicants respectfully submit that the Leidich Patent is not within the field of "inventor's endeavor". Applicants' field of endeavor is the field of medical devices generally and, more particularly, is the field of catheters for facilitating medical fluid infusion into and aspiration from a body. In contrast, the Leidich Patent's field of endeavor is valves for taps for beer and other liquids. (See Leidich Patent, page 1, lines 12-14). The Leidich Patent is in no way concerned with catheters or with

any medical devices or medical applications. Therefore, Applicants respectfully submit that the Leidich Patent is not within Applicants' field of endeavor; thus the answer to the first part of the non-analogous art two-part test should be "NO".

Turning to the second part of the test, it is now necessary to establish the problem with which Applicants were involved. As stated in Applicants' specification, one of the objects the present invention is to provide a catheter which has a variety of radial and non-radial slits to facilitate aspiration of fluids from and infusion of fluids to a patient's circulatory system. In sharp contrast, the Leidich Patent addresses a need to create a valve which prevents the accidental escape of air, gas, or fluid from a barrel or cask during the process of tapping. Leidich, Col 1 line 14. "A reference is reasonably pertinent if, ... it is one which, because of the matter with which it deals logically, would have commended itself to inventor attention in considering his problem." In re Clay, 966 F.2d 656,659 (Fed. Cir. 1992). It is respectfully submitted that problems associated with tapping kegs are not ones which would have commended themselves to inventors in devising improved catheters.

The Leidich Patent's particular problem was in no way pertinent to the problem addressed by Applicants, nor would this reference have logically commended itself to Applicants'

attention. "If reference disclosure relates to the same problem as addressed by the claimed invention, that fact supports use of that reference in an obviousness rejection", In re GRAP Inc., 35 U.S.P.Q. 2d 1116, 1120 (Fed. Cir. 1995). Therefore, the answer to the second part of the two-part test should also be "NO". With each part answered in the negative, Applicants respectfully submit that the Leidich Patent should be considered as non-analogous art, and therefore cannot be used for an obviousness rejection.

In addition, Applicants respectfully submit that, even if the Leidich Patent is considered analogous art, neither of the cited references provides any suggestion, incentive or motivation for the combination as suggested by the Examiner. "Multiple cited prior art references must suggest the desirability of being combined and the reference must be viewed without the benefit of hindsight afforded to the disclosure." (emphasis added) In re Paulsen, 30 F.3d 1475, 1482 (Fed. Cir. 1994). "The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in order to solve the problem." Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 679 (Fed. Cir. 1998). Applicants respectfully submit that *there is no motivation or incentive to combine* the Desai Patent with the Leidich Patent to allegedly teach or suggest Applicants' claimed invention.

Furthermore, the Examiner is reminded that "the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991).

As described above, the Leidich Patent describes an invention and methods for "Improvements in Automatic Valves for Beer and other Liquid Taps" for preventing accidental escape of air, gas, or fluid from the barrel or cask during the process of tapping" Col 1, lines 5 - 14. In contrast, the Desai Patent relates to an end hole valve which "functions to curtail undesirable jet effects and to decrease the amount of contrast material and radiation required for optimal angiographic results." Desai Patent, Col 2, line 43. Thus, since the Desai Patent and the Leidich Patent describe totally different devices (a catheter / a valve for a beer tap), useful in completely separate fields, it is respectfully submitted that neither of these references provides any suggestion, incentive or motivation for the combination and that this combination is an improper hindsight reconstruction.

There are several points in which the Leidich and Desai patents seem to teach away from the proposed combination. Desai asserts that, "[i]nclusion of valve 40 will reduce the quantity of contrast material required for effective angiography and will

eliminate end-hole jets and their concomitant effects." Col 5, line 45. The end-hole jet phenomenon occurs as a result of external fluid injected into an elongate catheter being expelled from a hole in the distal end of the catheter at a high velocity due to the small size of the end hole. Therefore, a purpose of the valve 40 in Desai is to prevent the movement of fluid from the tube 20 *distally* out of the end of the catheter into the bloodstream.

As stated above, a purpose of the valve A of Leidich is to prevent accidental escape of air, gas, or fluid *from the barrel or cask* during the process of tapping" Col 1 line 14 (emphasis supplied). Said another way, the purpose of the valve A in Leidich is to prevent the movement of fluid from the cask *proximally* past the valve A. Leidich makes no disclosure concerning the movement of air, gas, or fluid *distally* and Desai makes no mention of fluid moving *proximally*.

It is respectfully submitted that neither Desai nor Leidich shows or suggests a medical device comprising an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter; and a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface as recited in amended claim 43.

Accordingly, Applicants respectfully submit that independent claim 43 is neither shown nor suggested by the above-cited references either taken alone or in combination and that this rejection should be withdrawn. Because claims 44 and 46 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable for the same reasons as indicated above.

It is respectfully submitted that the combination of Desai and Leidich is not supported by any motivation provided within either of these references and that this combination of references should no longer be applied.

Claim 45 stands rejected as obvious over Desai in view of Leidich and further in view of Phelps et al. (U.S. Patent No. 6,419,659). The Examiner stated, in support of the rejection, that Desai shows a device as claimed except for the element of a collar disposed at the distal end of the catheter, but that Phelps discloses a collar 46 disposed adjacent the catheter's distal-most end. The Examiner further stated that it would have been obvious for one of ordinary skill in the art to combine the above mentioned prior art and that "doing so would provide an attending physician with means for determining the location of the catheter by magnetic or electromagnetic means (Phelps column 4, lines 30-35)."

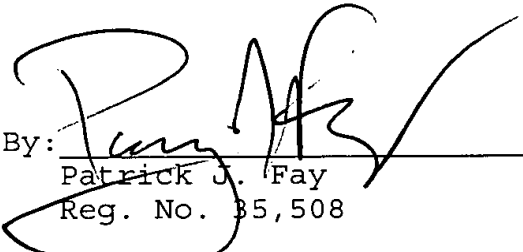
It is respectfully submitted that claim 45 is allowable

for the same reasons stated above in regard to claims 43, 44 and 46.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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By: 
Patrick J. Fay
Reg. No. 35,508

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, New York 10038
Tel: (212) 212-619-6000
Fax: (212) 208-6819